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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,381

06/02/2006

Kenichi Senda

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KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER

SANDERS, KRIELLION ANTONETTE

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,381	Applicant(s) SENDA ET AL.	
	Examiner Kriellion A. Sanders	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/05, 2/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether applicant intends the present claims to recite a copolymer of 3-hydroxybutylate and 3- hydroxyhexanoate or a copolymer of 3-hydroxybutyrate and 3-hydroxyhexanoate. It is noted that applicant refers to a copolymer of 3-hydroxybutyrate and 3-hydroxyhexanoate (PHBH copolymer) in Example 4 of his specification at page 15. No reference to a copolymer of 3-hydroxybutylate and 3- hydroxyhexanoate is found in applicant's specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/64498.
3. The World patent discloses suspensions of polymer particles, and more particularly, methods for producing suspensions of amorphous polymer particles, especially of

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polyhydroxyalkanoate polymers, (PHAs). The patent indicates that, “ The PHAs can be derived from biological systems including bacteria and genetically engineered plant crops. In bacterial systems, the PHAs are accumulated intracellularly as granular inclusion bodies. PHA also can be produced in genetically engineered plant crops.” “The particle size of the crystalline or partly crystalline polymer slurry feed is an important consideration in the methods described herein. Generally, PHA powders from aqueous isolation processes are crystalline with a particle size of at least 20-50 μm . The suspension medium is preferably water, although it can be an aqueous solution with at least about 50% (by weight) water with the balance including one or more water-miscible organic solvents, such as alcohols, ketones, acetone, and DMSO.” The suspension can include one or more additives, such as surfactants, dispersants, emulsifiers, soaps, or detergents, any of which can be added before, during, or after thermal treatment.

4. The polymer particles of the World Patent have a median particle size of between about 0.1 and 1 μm .

5. The polymers may be poly-3-hydroxybutyrate-co-3-hydroxyhexanoate or poly-3-hydroxybutyrate-co-3-hydroxyvalerate.

6. See pages 6, lines 29-33, page 7, lines 1-33, and claims 1, 7, 9, 10, 12 and 19.

7. The patented invention meets the limitations of applicant's claims with the following exceptions:

8. The reference is silent as to molecular weight and flexural modulus. However, because the polymers are essentially the same as applicant's they are expected to possess properties like those of applicant's claims or to be readily synthesized to possess properties like those of applicant's claims, in a manner to achieve the objectives of the invention.

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9. It is noted that applicant refers to a copolymer of 3-hydroxybutyrate and 3-hydroxyhexanoate (PHBH copolymer) in Example 4 of his specification at page 15.

Claim Rejections - 35 USC § 103

10. Claims 5 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/64498 as applied to claims 1-4 and 6-9 above, and further in view of EP 0 809 669.

The EP 0 809 669 relates to a process of recovering PHA from a suspension of particles of PHA in water by maintaining the suspension at a temperature at which the PHA melts, at least partly forming a layer of molten PHA, and separating the PHA layer; and (b) a process of making a PHA latex by shearing separated liquid PHA with a surfactant and water.

The molecular weight of the PHA is over 50000, especially over 100000,

A preferred PHA of the invention is co-polymer polyhydroxybutyrate-co-valerate, (PHBV).

The polymer co-polymer polyhydroxybutyrate-co-valerate, (PHBV) is equated by the World Patent to poly-3-hydroxybutyrate-co-3- hydroxyhexanoate at page 7 of that reference. See the EP patent at paragraphs [0001] and [0012]. The latter process of the EP reference wherein liquid PHA is sheared reads upon the limitations of applicant's invention.

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to separate the PHBV copolymer particles of WO 99/64498 by a process utilizing mechanical shearing as taught by EP 0 809 669 with the expectation of achieving appreciable separation results, absent a clear showing of unexpected results attributable to such a variation. This is particularly true since the World reference equates the PHA polymers.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kriellion A. Sanders whose telephone number is 571-272-1122. The examiner can normally be reached on Monday through Thursday 8:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kriellion A. Sanders/

Primary Examiner, Art Unit 1796

Kriellion A. Sanders
Primary Examiner
Art Unit 1796

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